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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/210,952	12/15/1998	MICHAEL M. FAIZILBER	2314-147	7780

6449 7590 05/21/2002

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SUITE 800  
WASHINGTON, DC 20005

EXAMINER

NOLAN, PATRICK J

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 05/21/2002

26

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/210,952**

Applicant(s)  
**Fainzilber et al.**

Examiner  
**Patrick J. Nolan**

Art Unit  
**1644**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Oct 24, 2001
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 20-31 and 33-36 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20-26 is/are rejected.
- 7) ☒ Claim(s) 27-31 and 33-36 is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                              | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | 6) <input type="checkbox"/> Other:  |

Art Unit: 1644

### **DETAILED ACTION**

1. The Examiner of your application in the Patent and Trademark Office has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Patrick Nolan in Art Unit 1644, Technology Center 1600 ((703) 305-1987).
2. Claims 20-31 and 33-36 are currently pending.

#### **The following new ground of rejection is necessitated by Applicant's amendment filed 10-24-01**

The following is a quotation of the first paragraph of 35 U.S.C. §112:

"The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention."

3. Claims 20-26 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabled for use of the specific conopeptides PnVIIA and TxVIIA as agonists of neuronal pacemaker cation channels does not reasonably provide enablement for use of the conopeptides of SEQ ID NO:6-8, 10-15 wherein Xaa<sub>2</sub> is  $\gamma$ Glu or Glu, or Xaa<sub>3</sub> is Hyp or Pro, or wherein Xaa<sub>1</sub> is Trp or 6-bromo-Trp, or the conopeptides Tx6.4, Tx6.9, Tx6.6 and Tx6.5 (SEQ ID NO:6-8, 10-11), wherein Xaa<sub>1</sub> is Trp, Xaa<sub>2</sub> is  $\gamma$ Glu and Xaa<sub>3</sub> is Hyp and the C-terminus has a free carboxyl group; Gm6.7 and Mr6.1 (SEQ ID NO:12-13) wherein Xaa<sub>1</sub> is Trp, Xaa<sub>2</sub> is  $\gamma$ Glu, and Xaa<sub>3</sub> is Hyp; and Mr6.2 and Mr6.3 (SEQ ID NO:14-15) wherein Xaa<sub>1</sub> is Trp, Xaa<sub>2</sub> is  $\gamma$ Glu, and the C-terminus is amidated. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with the claims, for reasons set forth in Paper No. 20.

Applicant's arguments filed 10-24-01 have been fully considered but are not found persuasive.

Applicant argues the substitutions claimed are well known in the art of conopeptides and the Shen et al., article does not teach slight species variation is the hypervariable loop regions can result in distinct pharmacological activities.

However, Shen et al., does teach that however slight species variation is the hypervariable loop regions can result in distinct pharmacological activities, and furthermore, Applicant's assertion that well known substitutions is not relevant since the substitutions were in other distinct conopeptides that only share source of material in common, not biological activity as is clearly taught by Shen et al.

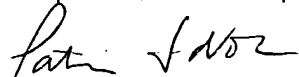
4. Claims 27-31 and 33-36 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1644

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Monday through Friday from 8:30 am to 4:30 pm.

7. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 305-7939. Any inquiry of a general nature relating to the status of this application or proceeding should be directed to the Group receptionist, whose telephone number is (703) 308-0196.



Patrick J. Nolan, Ph.D.

Primary Examiner, Group 1640

5/19/02